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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 09/272,809  | 03/19/1999  | JOHN CLARK LAGARIAS  | 23070-943               | 6118             |
| 7590  | 04/01/2005  |                      | EXAMINER                |                  |
| LAW OFFICES OF JONATHAN ALAN QUINE<br>PO BOX 458<br>ALAMEDA, CA 94501 |             |                      | HINES, JANA A           |                  |
|   |             |                      | ART UNIT                | PAPER NUMBER     |
|   |             |                      | 1645                    |                  |
|   |             |                      | DATE MAILED: 04/01/2005 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                      |  |
|------------------------------|------------------------|----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>  |  |
|                              | 09/272,809             | LAGARIAS, JOHN CLARK |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>      |  |
|                              | Ja-Na Hines            | 1645                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 January 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-19 and 21-32 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-19 and 21-32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

***Amendment Entry***

1. The amendment filed January 3, 2005 has been entered. The examiner acknowledges the amendment to the specification. Claims 2 and 20 have been cancelled. Claims 1, 3-19 and 21-32 are under consideration in this office action.

***Withdrawal of Rejection***

2. The written description rejection of claims 1, 3-19 and 21-32 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of applicants' arguments.

***New Grounds of Rejection***

***Claim Objections***

3. Claims 6 and 21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 6 and 21 recite that the apoprotein polypeptide consist of a lyase domain, however claims 1 and 17 are already comprise a apoprotein polypeptide comprising a lyase domain.

4. Claims 5, 17 and 24 are objected to because of the following informalities: Claims 5 and 24 recite the word "aipoprotein" instead of apoprotein. Claim 17 recites the word "an-apoprotein". Appropriate correction is required.

***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1,3,9-21 and 27-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-7, 9-11, 13-16, 19, 21-22 and 24-26 of U.S. Patent No. 6,014,014. Although the conflicting claims are not identical, they are not patentably distinct from each other because US Patent 6,046,014 has claims drawn to a composition comprising a moiety to be detected linked to a fluorescent adduct consisting of a phytochrome apoprotein and a bilin chromophore. The apoprotein polypeptide is selected from the group consisting of a plant apoprotein, an algal apoprotein, and a cyanobacterial apoprotein and consist of a chromophore domain. The bilin is a tetrapyrrole or a phycoerythrobilin. The moiety is biomolecule selected from the group consisting of a protein, glycoprotein, antibody and a nucleic acid. The Patent also claims a method of detecting the presence of a biomolecule in a sample, the method comprising: providing a sample comprising a

biomolecule linked to a fluorescent adduct consisting of a phytochrome apoprotein and a bilin chromophore; contacting the sample with light ~~which~~ causes the fluorescent adduct to emit light; and detecting the emitted light, thereby detecting the presence of the biomolecule. The method requires that the light have a wavelength of about 570 nm or 590 nm. The apoprotein polypeptide used within the method is selected from the group consisting of a plant apoprotein, an algal apoprotein, and a cyanobacterial apoprotein and consist of a chromophore domain. The bilin used within the method is a tetrapyrrole or a phycoerythrobilin. And the moiety used within the method is biomolecule selected from the group consisting of a protein, glycoprotein, antibody and a nucleic acid.

The claims of the instant application are drawn to a composition comprising an apoprotein polypeptide of between about 190 amino acids to about 400 amino acids, which apoprotein polypeptide comprises a lyase domain, wherein said apoprotein polypeptide is selected from the group consisting of a plant apoprotein, an algal apoprotein, and a cyanobacterial apoprotein. The apoprotein is covalently linked to a bilin to form a fluorescent adduct, and the bilin is a tetrapyrrole or a phycoerythrobilin. The fluorescent adduct is linked to a biomolecule, wherein the biomolecule selected from the group consisting of a protein, glycoprotein, antibody and a nucleic acid. The instant claims are also drawn to a method of detecting the presence of a biomolecule in a sample, the method comprising: providing a sample comprising a biomolecule linked to a fluorescent adduct consisting of a bilin and an apoprotein of between about 190 amino acids to about 400 amino acids, which apoprotein polypeptide comprises a lyase domain, wherein said apoprotein polypeptide is selected from the group consisting of a

plant apoprotein, an algal apoprotein, and a cyanobacterial apoprotein; contacting the sample with light with causes the fluorescent adduct to emit light; and detecting the emitted light, thereby detecting the presence of the biomolecule. The method requires that the light have a wavelength of about 570 nm or 590 nm. The bilin used within the method is a tetrapyrrole or a phycoerythobilin. And the moiety used within the method is biomolecule selected from the group consisting of a protein, glycoprotein, antibody and a nucleic acid.

The patented claims are drawn to a composition comprising a moiety to be detected linked to a fluorescent adduct consisting of a phytochrome apoprotein and a bilin chromophore wherein the apoprotein polypeptide is selected from the group consisting of a plant apoprotein, an algal apoprotein, and a cyanobacterial apoprotein, however the instant claims recite claims which are an obvious variation of the patented claims. The instant claims state that the apoprotein polypeptide is between about 190 to about 400 amino acids, while the patented claims are silent with respect to the number of amino acids, however the term encompasses both naturally occurring and variant polypeptides capable of forming an adduct with a bilin component as defined by US Patent 6,046,014, column 5 lines 8-16. The apoprotein polypeptide of the instant claims meets that limitation. Moreover, the apoprotein polypeptide of the instant claims is encompassed by the apoprotein polypeptide of US Patent 6,046,014. It is noted that the terms "chromophore domain" or "lyase domain" are equivalent and refer to the apoprotein N-terminal subsequence sufficient for lyase activity and thereby form a covalent bond between the apoprotein and the bilin. See pages 7-8 of the instant

specification. Therefore the chromophore domain" language of the patent and the "lyase domain" of the instant claims are both requiring the composition to comprise the same domains. Moreover, both the patented claims and the instant claims require that the bilin is a tetrapyrrole or a phycoerythrobilin and that the moiety is biomolecule selected from the group consisting of a protein, glycoprotein, antibody and a nucleic acid.

Therefore the instant claims are an obvious variation of the patented claims.

US Patent 6,046,014 is also drawn to a method of detecting the presence of a biomolecule in a sample, the method comprising: providing a sample comprising a biomolecule linked to a fluorescent adduct consisting of a phytochrome apoprotein and a bilin chromophore; contacting the sample with light which causes the fluorescent adduct to emit light; and detecting the emitted light, thereby detecting the presence of the biomolecule. The instant claims recite the same method steps. Moreover, the method steps use the same composition, see the explanation above. Therefore, both the patented claims and the instant claims are drawn to the same method of detection thus; making the instant claims an obvious variation of the patented claims.

Thus a person of ordinary skill in the art would conclude that the inventions defined in the claims are obvious variations of the inventions defined in the claims of the patent. Therefore, neither the composition nor the method steps of the instant application are patentably distinct from patent, and the invention defined in the instant claims is an obvious variation of the invention defined in the claim of a patent.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines *JH*  
March 21, 2005

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